

ORIGINAL ARTICLE

Validity and Reliability of Seattle Angina Questionnaire Japanese Version in Patients With Coronary Artery Disease

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Purpose The aim of this study was to evaluate the validity and reliability of the Seattle Angina Questionnaire, Japanese version (SAQ-J) as a disease-specific health outcome scale in patients with coronary artery disease.

Methods Patients with coronary artery disease were recruited from a university hospital in Tokyo. The patients completed self-administered questionnaires, and medical information was obtained from the subjects' medical records. Face validity, concurrent validity evaluated using Short Form 36 (SF-36), known group differences, internal consistency, and test-retest reliability were statistically analyzed.

Results A total of 354 patients gave informed consent, and 331 of them responded (93.5%). The concurrent validity was mostly supported by the pattern of association between SAQ-J and SF-36. The patients without chest symptoms showed significantly higher SAQ-J scores than did the patients with chest symptoms in 4 domains. Cronbach's alpha ranged from .51 to .96, meaning that internal consistency was confirmed to a certain extent. The intraclass correlation coefficient of most domains was higher than the recommended value of 0.70. The weighted kappa ranged from .24 to .57, and it was greater than .4 for 14 of the 19 items.

Conclusions The SAQ-J could be a valid and reliable disease-specific scale in some part for measuring health outcomes in patients with coronary artery disease, and requires cautious use. [*Asian Nursing Research* 2010;4(2):57–63]

Key Words coronary artery disease, reliability, scale, validity



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INTRODUCTION

According to statistics collected by the Ministry of Health, Labour and Welfare, approximately 900,000 people have been diagnosed with coronary artery disease (CAD); CAD accounts for over half of cardiovascular disease making it the second leading cause of death in Japan (Japan Ministry of Health, Labour, and Welfare, 2005). Therefore, strategies for the administration of efficient treatment and secondary prevention of this disease merit extensive investigation. Additionally, it is important to evaluate the health outcomes, including the health-related quality of life, as well as the mortality and physiologic measures in CAD patients.

When assessing health outcomes in CAD patients, a disease-specific scale is preferred to a generic one for the evaluation of the general condition of the patients and the response to treatment (Ikegami, Fukuhara, Shimotsuma, & Ikeda, 2001). The Seattle Angina Questionnaire (SAQ) is a disease-specific health outcome scale developed in 1995 to assess the health outcomes of CAD patients (Spertus et al., 1995). It has been used in many previous studies (Chen, Daley, & Thibault, 1996; Graham et al., 2006; Spertus et al., 2006; Weintraub et al., 2008). While the SAQ has been translated into Japanese by Cardiovascular Outcomes Incorporated (USA), the validity and reliability of the Japanese version have not been psychometrically tested. To confirm the SAQ is an accurate, stable, valid and reliable scale in measuring the health outcomes in Japan, its accuracy, stability, validity and reliability have to be tested before use. The present study aims to evaluate the validity and reliability of the Japanese version of the SAQ (SAQ-J) in Japanese patients with CAD.

METHODS

The present study was a cross-sectional, mail-based psychometric survey. It was approved by the university institutional review board.

Pilot study for face validity

In June 2007, SAQ-J was administered to 8 patients, who were regularly followed up at a university hospital

in Tokyo. The time taken to complete the questionnaire was approximately 5 minutes, and no confusing or unclear items were reported by the patients.

Data collection

From July 2007 to March 2008, patients were recruited from the inpatient ward and outpatient department at a university hospital in Tokyo. Patients were eligible for participating in this study if they had been diagnosed with CAD, were aged 20 years or older, were able to read and write in Japanese, and did not have impaired cognitive function.

In the outpatient setting, the study procedure was explained to patients who met the eligibility criteria. Patients then signed the consent forms in a private room. Next, they were given the first questionnaires including SAQ-J, Short Form 36 (SF-36) and details regarding items such as marital status, education, employment, living status and history of smoking; they were asked to fill out the questionnaires at home and send them back by post. The patients who failed to respond by 2 weeks were sent reminders. In the hospital setting, the questionnaires were given after obtaining informed consent in a private room and collected within a few days.

Two weeks after the first survey was completed, the second SAQ-J was mailed or handed to the patients who had responded to the first sets of measures and who had agreed to have the SAQ-J administered twice. This was done for the evaluation of test-retest reliability. The time interval for this assessment was from 2 to 3 weeks in this study.

Relevant medical information regarding specifications such as history of myocardial infarction, percutaneous coronary intervention, and coronary artery bypass grafting (CABG), number of affected vessels, left ventricular ejection fraction, comorbidities, and disease duration was obtained from the patients' medical records.

Self-administered health outcome scales

The SAQ is a 19-item self-administered questionnaire and consists of 5 domains: physical limitation (9 items), anginal stability (1 item), anginal frequency (2 items), treatment satisfaction (4 items) and quality

of life (3 items). Each item is answered using 5- or 6-point Likert scales (Spertus et al., 1995). The score for a particular domain was calculated by adding the item scores for that domain; the domain scores were converted to a 0–100 scale, with 100 representing the best outcome (Spertus et al.).

The Short Form 36 version 2 Japanese (SF-36), which was used for assessing the concurrent validity of the SAQ-J, is a generic health outcome scale consisted of 36 items covering eight domains: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health (Fukuhara & Suzukamo, 1994). The physical component summary and the mental component summary scores were computed from the scores of these eight domains (Fukuhara & Suzukamo). However, the usage of summary scores of SF-36 Japanese is not recommended due to the difference in domain structure between the Japanese version and the original version. Thus, these summary scores are not shown in the present study.

Statistical analyses

Patient characteristics and each domain score of the SAQ-J were evaluated by descriptive analysis; floor and ceiling effects were determined.

To assess the concurrent validity of the SAQ-J, Pearson's product moment correlation coefficient between the scores of the SAQ-J and SF-36 was computed. As known group differences, the SAQ-J scores of patients with and without chest symptoms were evaluated with the Mann-Whitney *U* test.

Internal consistency was assessed by computing Cronbach's alpha. Test-retest reliability was assessed by computing the intraclass correlation coefficient of each domain and the weighted kappa value of each item.

Statistical analyses were performed using SPSS version 14.0 (SPSS Inc., Chicago, IL, USA) for Windows.

RESULTS

Data collection

A total of 356 patients were eligible to participate in this study; 354 gave informed consent, and 335

responded. After excluding 4 patients who had missing items on more than 90% of the questionnaires, the final number of candidates who participated in the first study was 331 (93.5%).

A total of 253 patients signed the consent form to participate in the second study for the assessment of test-retest reliability. The second SAQ-J questionnaires were sent to 230 of the 253 patients who responded to the first study, and 202 (86.0%) patients completed the questionnaires.

Patient characteristics

Table 1 shows the characteristics of the study participants: 262 (78.4%) patients were male, the mean age was 68.1 ± 10.4 years, and 23.9% were inpatients.

Floor and ceiling effects and domain scores of the SAQ-J

The floor and ceiling effects and domain scores of the SAQ-J are shown in Table 2. Many patients showed a ceiling effect in the case of the anginal frequency domain.

Validity of the SAQ-J

Table 3 shows the correlation between SAQ-J and SF-36, which was used to assess concurrent validity. The physical limitation domain of the SAQ-J was more strongly correlated with Physical Functioning and Role Functioning than with the other domains of the SF-36. Anginal frequency was more closely correlated with Physical Functioning and Bodily Pain than with the other domains. The treatment satisfaction and quality of life domains of the SAQ-J were highly correlated with General Health, Vitality and Mental Health. With regard to the known group differences, shown in Table 4, the patients without chest symptoms exhibited significantly higher SAQ-J scores than those who had poor scores for the physical limitation, anginal frequency and quality of life domains.

Reliability of the SAQ-J

Table 5 shows the internal consistency and the test-retest reliability of the SAQ-J. In the case of the physical limitation and treatment satisfaction domains,

Table 1*Medical and Demographic Characteristics*

Characteristics (n)	n	% ^a
Gender (331)		
Male	262	78.4
Employment status (323)		
Employed	156	48.3
Living alone (326)	41	12.6
Marital status (322)		
Single	25	7.8
Married	246	76.4
Divorced	18	5.6
Widowed	33	10.2
Educational background (321)		
Middle high school	54	16.8
High school	127	39.6
Community college	29	9.0
College	111	34.6
Smoking status (322)		
Current	41	12.7
Past	183	56.8
Never	98	30.4
Previous myocardial infarction (324)	108	33.4
Previous PCI (324)	170	52.5
Previous CABG (324)	144	44.4
Hyperlipidemia (324)	208	64.2
Hypertension (323)	234	72.4
Diabetes (324)	167	51.5
Number of diseased coronary vessels ^b (324)		
1	68	21.0
2	88	27.2
3	132	40.7
Left main trunk lesion ^b (323)	43	13.3
Medication (324)		
Nitrate	140	43.2
β-Blocker	138	42.6
Calcium antagonist	160	49.4
Statin	193	59.6
Antiplatelet	292	90.1
ACE inhibitor	180	55.5

(Contd)

Patient status (331)

Inpatient 79 23.9

M ± SD

Age (331) 68.1 ± 10.4

Disease duration (320; yr) 5.7 ± 7.5

Body mass index (326) 23.7 ± 4.1

Left ventricular ejection fraction (317; %) 60.0 ± 12.4

Note. PCI = Percutaneous coronary intervention; CABG = Coronary artery bypass graft; ACE = angiotensin-converting enzyme. ^aPercentages do not add up to 100% due to rounding; ^bover 75% of stenosis in the vessels.

Cronbach's alpha exceeded .7. The intraclass correlation coefficient of all domains, except for the anginal frequency domain, was .70. The weighted kappa was .24–.57.

DISCUSSION

Measuring health outcomes with the SAQ-J would be a substantial achievement and would be of considerable importance in the clinical and research settings since very few CAD-specific scales are currently applicable to the Japanese population.

Regarding the face validity of the SAQ-J, it was pilot-tested before proceeding to the major field study, and none of the item was reported as confusing or unclear. Consequently, the face validity of SAQ-J was confirmed.

As mentioned above, the ceiling effect of the SAQ-J was observed in many patients. It was because the majority of the participants in the present study were recruited from an outpatient department and were not severely ill. This was probably associated with better outcomes.

As predicted, the concurrent validity was largely supported by the pattern of association between SF-36 and SAQ-J (Garratt, Hutchinson, & Russell, 2001; Hofer, Benzer, Schussler, von Steinbuchel, & Oldridge, 2003; Pettersen, Reikvam, & Stavem, 2005; Spertus et al., 1995). The physical limitation, treatment satisfaction, and quality of life domains

Table 2*Floor and Ceiling Effects, Domain Scores, and Internal Consistency of the Seattle Angina Questionnaire-Japanese Version (SAQ-J)*

SAQ-J (n)	Floor ^a %	Ceiling ^b %	Domain score $M \pm SD$	Cronbach's alpha
Physical limitation (307)	0.7	16.9	74.8 \pm 22.0	.96
Anginal stability (312)	2.2	8.0	52.2 \pm 17.1	N/A
Anginal frequency (324)	0.0	73.1	93.5 \pm 13.6	.51
Treatment satisfaction (319)	0.3	26.6	83.3 \pm 15.1	.78
Quality of life (320)	0.6	10.0	71.9 \pm 20.1	.67

Note. N/A = not applicable. ^aLowest scale score; ^bhighest scale score.

Table 3*Concurrent Validity of the Seattle Angina Questionnaire-Japanese Version (SAQ-J)*

SAQ-J (n)	SF-36									
	PF	RF	BP	GH	VT	SF	RE	MH	PCS	MCS
Physical limitation (307)	.78 ^{a*}	.66 ^{a*}	.43 ^{a*}	.37 ^{a*}	.51 ^{a*}	.52*	.58*	.33*	.76 ^{a*}	.34*
Anginal stability (312)	.06	-.02	.04	.04	.10	.03	-.03	.08	.04	.04
Anginal frequency (324)	.36 ^{a*}	.26*	.38 ^{a*}	.23 ^{a*}	.29 ^{a*}	.21*	.29*	.30*	.37 ^{a*}	.22*
Treatment satisfaction (319)	.19*	.23*	.20 ^{a*}	.30 ^{a*}	.36 ^{a*}	.28*	.31*	.33 ^{a*}	.21*	.37*
Quality of life (320)	.33*	.42*	.34 ^{a*}	.42 ^{a*}	.42 ^{a*}	.41*	.47*	.43 ^{a*}	.39 ^{a*}	.46*

Note. SF-36 = Short Form-36; PF = physical functioning; RF = role functioning-physical; BP = bodily pain; GH = general health; VT = vitality; SF = social functioning; RE = role functioning-emotional; MH = mental health; PCS = physical component summary; MCS = mental component summary. ^aPredicted substantial associations. Pearson's product-moment correlation coefficient: * $p < .01$.

Table 4*Known-Group Differences of the Seattle Angina Questionnaire-Japanese Version (SAQ-J)*

Domain score	Symptomatic (n = 60)	Asymptomatic (n = 263)	p
	$M \pm SD$	$M \pm SD$	
SAQ-J			
Physical limitation	58.8 \pm 24.6	73.8 \pm 20.9	< .001
Anginal stability	50.9 \pm 29.1	52.8 \pm 13.4	.27
Anginal frequency	75.0 \pm 19.7	97.5 \pm 7.6	< .001
Treatment satisfaction	75.4 \pm 18.3	85.0 \pm 13.8	< .001
Quality of life	53.5 \pm 22.8	75.8 \pm 18.4	< .001

of the SAQ-J were moderately correlated with Role Functioning-Emotional than with other domains, which were expected to have higher correlation. Other because the generic SF-36 scale was used; however, the results were equivalent to those obtained with other versions of the SAQ.

Known-group differences of the SAQ-J were verified. Because the patients' medical records did not include data regarding the division of patients according to the Canadian Cardiovascular Society Classification and because most patients in this study had relatively good cardiac function, data from patients

Table 5*Test-retest Reliability of the Seattle Angina Questionnaire-Japanese Version (SAQ-J)*

SAQ-J (n)	ICC	Weighted κ
Physical limitation (199)	.77	.24–.48
Anginal stability (192)	.41	.38
Anginal frequency (198)	.72	.56
Treatment satisfaction (189–196)	.79	.34–.57
Quality of life (189–198)	.74	.35–.49

Note. ICC = intraclass correlation coefficients.

with or without chest symptoms were used. In previous studies, patients with chest symptoms showed lower health outcome scores than those without chest symptoms (Nishiyama et al., 2005). As hypothesized, asymptomatic patients showed higher SAQ-J scores than the symptomatic patients who had poor scores for all domains, except the anginal stability domain. The anginal stability domain included a question about chest symptoms present 1 month before the survey and the control of these symptoms.

Cronbach's alpha was used to assess internal consistency, which was confirmed to a certain extent. The physical limitation and treatment satisfaction domain scores exceeded .7—the suggested value that indicates scale validity (Fayers & Machin, 2007). The alpha values for the anginal frequency and quality of life domains were lower than the recommended values; however, the alpha for the quality of life domain (.67) was acceptable.

The test-retest reliability of the SAQ-J was confirmed. The intraclass correlation coefficients of the scores of all domains of the SAQ-J, except for the anginal stability domain, exceeded the recommended value of .7 (Fayers & Machin, 2007). Compared to the original version, the Japanese version had better results with regard to the score for the anginal stability domain, despite the score not being greater than .7. Even though SAQ-J has anginal stability and anginal frequency domains that might be changed over time, we tested the test-retest reliability following the validation study of the original version. The weighted kappa exceeded the recommended value

of .4 for 14 of the 19 items (Fayers & Machin). The five items for which the weighted kappa was below .4 showed a high rate of concordance.

The generalizability of the findings of the present study is limited because of geographical limitations and disease severity. Further evaluation of the SAQ-J should be performed in community hospitals and should include severely ill patients.

CONCLUSION

The present study evaluated the validity and reliability of the SAQ-J, a disease-specific health outcome scale in Japanese patients with CAD. The validity and reliability of this scale were verified through a patient-based field study. The SAQ-J was found to be a valid and reliable scale in CAD patients in some part; therefore, it requires cautious use. Studies that focus on other samples are expected for the future studies.

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